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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/560,372 04/28/00 TALL

A 61766/JPW/GJ

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NEW YORK NY 10036

HM12/0913

EXAMINER

PARAS TR P

ART UNIT

PAPER NUMBER

1632
DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/560,372	Applicant(s) TALL, ALAN R.	
	Examiner Peter Paras	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 and 49, drawn to an ABC promoter having the nucleotide sequence set forth in Seq Id No: 1, a recombinant expression construct comprising the same, a cell transformed in vitro with the same expression construct, and an ABC gene operably linked to the same nucleotide sequence, classified in classes 536, 536, 435, 435, subclass 24.1, 23.5, 320.1, 325.
- II. Claims 15-25, drawn to a method of expressing foreign DNA in a cell, classified in class 435, subclass 91.1.
- III. Claims 26-43 and 45, drawn to a method of determining whether a chemical can modulate expression of the human ABC gene, classified in class 435, subclass 6.
- IV. Claim 44, drawn to a method of treating atherosclerosis, classified in class 514, subclass 44.
- V. Claims 46-47, drawn to a transgenic non-human mammal comprising an ABC promoter having the nucleotide sequence set forth in Seq Id No: 1, classified in class 800, subclass 14.
- VI. Claim 48, drawn to an unknown compound that modifies expression of the ABC gene, is unclassifiable.

- VII. Claim 49, drawn to an isolated ABC gene, classified in class 536, subclass 23.5.

Inventions I, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Groups I, V, VI, and VII have different modes of operation, different functions, and different effects. The products of Groups I, V, VI, and VII have different chemical structures and may be used in materially different methods. For example, the nucleotide sequence of Group I may be used as a probe in a hybridization assay, the transgenic mammal of Group V may be used as a model for disease, the unknown compound of Group VI may be used to modulate expression of the ABC gene, and the ABC gene of Group VII may be used to transform somatic cells *in vitro*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that require a separate search, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups II, III, and IV because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and

further comprising distinct methodologies and using different products. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups II, III, and IV restriction for examination purposes as indicated is proper.

The products of Inventions I, V, VI, and VII and the methods of Inventions II, III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Inventions I, V, VI, and VII and the methods of Inventions II, III, and IV have different functions, different modes of operation, and different effects. The methods of inventions II, III, and IV may use materially different products which have different chemical structures than the products of Inventions I, V, VI, and VII. The products of Inventions I, V, VI, and VII may be used in methods, other than the methods of Inventions II, III, and IV, having different method steps and requiring materially different products. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that would require a different search, restriction for examination purposes as indicated is proper.

A telephone call was made to Gary Gershik on August 15 to request an oral election to the above restriction requirement, but did not result in an election being made.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Peter Paras, Jr.
Art Unit 1632


DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600